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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,134	11/01/2000	Todd Siegel	00688081	4080

33448 7590 04/20/2006

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EXAMINER

PARADISO, JOHN ROGER

ART UNIT PAPER NUMBER

3721

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/704,134	SIEGEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John R. Paradiso	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 4/4/2006 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/704134 is acceptable and a CPA has been established. An action on the CPA is attached.

### ***Claim Rejections***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over TAKEMASA ET AL (US 5765606) in view of BOUTHINETTE (US 6023916) and HAYES ET AL (US 6334980).

4. TAKEMASA ET AL discloses an automated pharmaceutical packaging machine in which pharmaceutical products are dispensed from an array of sources (7) to a corresponding funnel (33) (See Figure 8) and then into each cavity of a plurality of product package cavities (33) and transferring them into a product package member. (See TAKEMASA ET AL columns 4 and 5 and figure 6)

Art Unit: 3721

5. TAKEMASA ET AL does not specifically disclose the pharmaceutical products being dispensed into product package templates.

6. BOUTHINETTE discloses a packaging kit with product package template cavities corresponding to cavities of a product package member. (See BOUTHINETTE columns 5 and 6 and figures 2, 7, and 11.)

7. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of TAKEMASA ET AL by dispensing the pharmaceutical products into product package templates, as taught by BOUTHINETTE, in order to ensure facilitated product placement into popular compartmented containers.

8. The combination of TAKEMASA ET AL and BOUTHINETTE does not disclose the use of an X-Y mechanical drive to move the package templates.

9. HAYES ET AL discloses an apparatus in which a dispensing apparatus (602a-c) which dispenses specific quantities of fluid to specific places on a template (722) which is moved by an X-Y positioning table (606). An X-Y circuit (608) moves the positioning table so that the correct spots in the template are positioned under the correct dispensers. (See HAYES ET AL column 11 line 38 to column 12 line 19 and figure 9.)

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the X-Y positioning table, as taught by HAYES ET AL, in the combination of TAKEMASA ET AL and BOUTHINETTE in order to more accurately place the products.

Art Unit: 3721

11. Regarding claims 2 and 7, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pneumatic cylinders to move the parts of the combination of TAKEMASA ET AL, BOUTHINETTE, and HAYES ET AL in order to move the assemblies in an easily controllable manner, as taught by the admitted prior art..

12. Regarding claims 3 and 8, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the combination of TAKEMASA ET AL, BOUTHINETTE, and HAYES ET AL with any number of arrays and funnels, as determined to be most efficient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233

13. Regarding claim 6, the claimed “temporary storage member” is being read on the carrier of the templates in the combination of TAKEMASA ET AL, BOUTHINETTE, and HAYES ET AL.

### ***Response to Arguments***

14. Applicant’s arguments filed 4/4/2006 have been fully considered but they are not persuasive.

15. Applicant states on page 7 of his Response that “If Takemasa was used to place pharmaceuticals into a support 1 as taught by Bouthiette, such support would be required to be

Art Unit: 3721

placed beneath the inserting opening 6. ... Given the distance between the outlet 33B of the holder 33 of Takemasa and the recess 1' of the Bouthiette support 1, alignment between the outlet 33B and the recess 1' of the support 1 would be difficult and would likely result in inaccurate placement of the pharmaceuticals.”

However, this would only be the case if TAKEMASA ET AL were modified by “shoehorning” in the parts of BOUTHiette. The above rejection does not state specifically that the frame would be resized and the working parts resized as necessary to fit the teachings because it has been held that rearranging parts of an invention involves only routine skill in the art and in the modification of TAKEMASA ET AL by the teachings of BOUTHiette and HAYES ET AL, that all the parts would be resized to fit properly with each other so as to work according to the teachings disclosed and relied upon.

16. Applicant states on page 8 of his Response that “As detailed in its [sic] earlier response, Applicant asserts that the Examiner’s reliance on Hayes is improper because Hayes is directed to non-analogous art.

However, as stated in the Final Rejection mailed 5/4/2004, HAYES ET AL shows a dispensing apparatus (602a-c) which dispenses specific quantities of fluid to specific places on a template (722) which is moved by an X-Y positioning table (606). An X-Y (608) moves the positioning table so that the correct spots in the template are positioned under the correct dispensers. (See HAYES ET AL column 11:38-12:19 and figure 9.) Accordingly, Examiner maintains the rejection detailed above.

Art Unit: 3721

17. Applicant states on page 8 of his Response that "Further, as noted above, the configuration of Takemasa requires manual placement of a vial V on the holder 33 prior to dispensing the pharmaceutical. Bouthiette requires manual placement of the pharmaceuticals within the recesses 1' and does not disclose the use of a funnel or other source from which the pharmaceuticals are dispensed.

However, the motivation to use the X-Y positioning table, as taught by HAYES ET AL, in the combination of TAKEMASA ET AL and BOUTHIIETTE in order to more accurately place the products does not require manual placement and is actually enhanced by the automation of HAYES ET AL. Examiner also notes that it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

18. The questions stated on page 9 of Applicant's Response are obviated by paragraph 13 of the rejection above.


Art Unit: 3721

***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Paradiso. The examiner can normally be reached Monday-Friday, 9:30 p.m. – 6:00 p.m. (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada, can be reached at the number listed below.

Any inquiry of a general nature or relating to the status of this application should be directed to the 3700 Technology Center Receptionist.

  
\_\_\_\_\_  
Examiner John Paradiso: (571) 272-4466

April 17, 2006

Additional Phone Numbers:

Supervisor Rinaldi Rada: (571) 308-7135

Fax (Official): (571) 273-8300

Fax (Direct to Examiner) (571) 273-4466 (Drafts only)